

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Sosnowski et al. Examiner: Unassigned

> (Parent Application Examiner: S.A. Jiang)

Serial No.: 10/601,941 Group Art Unit: Unassigned

> (Parent Application Group Art Unit: 1617)

Filed: June 23, 2003 Docket No.: 1107-3 CIP

Confirmation No.: 7846 Customer No.: 33769

For: Composition And Method Dated: October 6, 2003

For Reducing The Risk Or

Progression Of

Cardiovascular, Glaucoma

And Tardive Dyskinesia Diseases

> I hereby certify this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to:

Commissioner for Patents Commissioner for Patents, P.O. Box 1450, P.O. Box 1450 Alexandria, VA 22313-1450

Alexandria, Virginia 22313-1450

Signed:

INFORMATION DISCLOSURE STATEMENT

Sir:

In order to fulfill the requirements of candor and good faith set forth in 37 C.F.R. §1.56, Applicants submit herewith the following Information Disclosure Statement in accordance with the provisions of 37 C.F.R. §1.97 and §1.98.

UNITED STATES PATENTS

<u>PATENTEE</u>	PATENT NO.	ISSUE DATE
Fogel	5,866,585	Feb. 2, 1999
Wakat	6,054,128	Apr. 25, 2000
Lipton et al.	5,922,773	Jul. 13, 1999
Rosenquist et al.	6,025,369	Feb. 15, 2000

FOREIGN DOCUMENTS

<u>INVENTOR</u>	PUBLICATION NO.	PUBLICATION DATE

Henderson, Janeel WO 00/37087 A1 June 29, 2000

NON-PATENT PUBLICATION

Bucci, L.R., FDA filing reference, August 27, 1999, pp.1 and 2.

Pei I. Ho et al., Multiple Aspects of Homocysteine Neurotoxicity: Glutamate Excitotoxicity, Kinase Hyperactivation and DNA Damage, Journal of Neuroscience Research 70:694-702 (December, 2002).

Seshadri, S. et al., *Plasma Homocysteine as a Risk Factor for Dementia and Alzheimer's Disease*, 1: N Engl J Med. 2002 Feb 14; 346(7):476-83.

Fonseca, V.A. et al., Insulin Sensitivity and Plasma Homocysteine Concentrations in Non-Diabetic Obese and Normal Weight Subjects, Atherosclerosis, 2003 March; 167(1):105-9.

A. Ambrosch et al., Relation Between Homocysteinaemia and Diabetic Neuropathy in Patients with Type 2 Diabetes, Diabetic Medicine, Volume 18, Issue 3, p.185, March 2001.

Pamela Moore et al., Apoptotic Cell Death in the Mouse Retinal Ganglion Cell Layer is Induced in Vivo by the Excitatory Amino Acid Homocysteine, Exp Eye Res. 73(1), pp. 45-57, July, 2001, Academic Press.

Centrum references, Whitehall Robins: Centrum Focused Formulas Heart and Centrum Herbals Ginkgo, from www.centrum.com.

McCully, Kilmer S., M.D., The Homocysteine Revolution "A Bold New Approach to the Prevention of Heart Disease", Keats Publishing, Los Angeles 1997, pp. 33, 64-65, 92-105, 137, 181.

Bleich S., Degner, D., Bandelow, B., von Ahsen, N., Ruther, E., Kornhuber, J., *Plasma Homocysteine is a Predictor of Alcohol Withdrawal Seizures*, Neuroreport 2000, Aug. 21 Abstract.

The above-referenced documents are listed on PTO Form 1449. We have enclosed the cited documents to facilitate reference to them.

Applicants are not aware of any other references to be identified at this time. If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact Applicants' attorney at the telephone number set forth below.

Respectfully submitted,

Gerald T. Bodner

Registration No. 30,449 Attorney for Applicants

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GTB/bj

FORM PTO-1
(Rev. 2-32)

OUT 0 8 2003

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Rey. 2-32) PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.	SERIAL NO.
1107-3 CIP	10/601,941
APPLICANT	CUSTOMER NO.
Sosnowski, et al.	33769
FILING DATE	GROUP ART UNIT
June 23, 2003	Unassigned

U.S. PATENT DOCUMENTS

	U.B. 11	TIENT DOCUMENT			
DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
5,866,585	2/2/99	Fogel			
6,054,128	4/25/00	Wakat			
5,922,773	7/13/99	Lipton et al.			
6,025,369	2/15/00	Rosenquist et al.			
	NUMBER 5,866,585 6,054,128 5,922,773	DOCUMENT NUMBER DATE 5,866,585 2/2/99 6,054,128 4/25/00 5,922,773 7/13/99	DOCUMENT NUMBER DATE NAME 5,866,585 2/2/99 Fogel 6,054,128 4/25/00 Wakat 5,922,773 7/13/99 Lipton et al.	DOCUMENT NUMBER DATE NAME CLASS 5,866,585 2/2/99 Fogel 6,054,128 4/25/00 Wakat 5,922,773 7/13/99 Lipton et al.	DOCUMENT NUMBER DATE NAME CLASS SUB CLASS 5,866,585 2/2/99 Fogel

FOREIGN PATENT DOCUMENTS

EXAMINER	DOCUMENT	DATE	COUNTRY	CLASS	SUB	TRANSLATION	
INITIAL	NUMBER				CLASS	YES	NO
	WO 00/37087 A1	6/29/00	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Bucci, L.R., FDA filing reference, August 27, 1999, pp. 1 and 2.
	Pei I. Ho et al., Multiple Aspects of Homocysteine Neurotoxicity:
	Glutamate Excitotoxicity, Kinase Hyperactivation and DNA Damage, Journal of Neuroscience Research 70:694-702 (December, 2002).
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EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE Rev. 2-32) PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 1107-3 CIP	SERIAL NO. 10/601,941	
E JCO	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT Sosnowski, et al.	CUSTOMER NO. 33769	
8 2003 E (L	Jse several sheets if necessary)	FILING DATE June 23, 2003	GROUP ART UNIT Unassigned	
& THAUCHER	Seshadri, S. et al., Plasma I and Alzheimer's Disease, 1			
	Fonseca, V.A. et al., Insulin Concentrations in Non-Dia Atherosclerosis, 2003 Marc	betic Obese and Normal	-	
	A. Ambrosch et al., Relatio Neuropathy in Patients with 18, Issue 3, p.185, March 2	h Type 2 Diabetes, Diabe		
	Cell Layer is Induced in Viv	coptotic Cell Death in the Mouse Retinal Gangli A Vivo by the Excitatory Amino Acid Homocyster 45-57, July, 2001, Academic Press.		
	Centrum references, Whitel Heart and Centrum Herbal.			
	McCully, Kilmer S., M.D., Approach to the Prevention Angeles 1997, pp. 33, 64-69	n of Heart Disease", Keat		
	Bleich S., Degner, D., Band Kornhuber, J., Plasma Hom			

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